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EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT PAPER NUMBER

1744

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/666,357	Applicant(s) WHITLEY, KENNETH W.	
	Examiner Nathan A. Bowers	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>121503, 043004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1) Claims 1, 2, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's admitted prior art in view of Keilman (US 4717668).

In paragraphs [0003] to [0007] of Applicant's specification, it is disclosed that the use of cylindrical roller bottles comprising a plurality of longitudinally extending pleats is well known in the art. Applicant teaches that these pleats are designed to increase the internal surface area of the bottle in order to enhance cell adhesion. The admitted prior art, however, does not teach that integrally formed circumferential ribs are constructed upon the fluted roller bottle in order to reinforce the cylindrical wall.

Keilman discloses a roller bottle container for cell growth culturing comprising a plurality of circumferential ribs (Figure 1:26) extending around the bottle. Column 1, line 60 to column 2, line 3 indicates that the ribs are formed integrally with the remainder of the flexible cylindrical wall that defines the roller bottle.

At the time of the invention, it would have been obvious to include a series of integrally formed circumferential ribs that to the roller bottles that are well known in the prior. Keilman states in column 3, line 55 to column 4, line 5 state that integrally formed ribbings are beneficial because they serve to increase the rigidity of the bottle, and

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decrease the likelihood that the bottle will collapse during use. The increased stability caused by the ribbings allows the width of sidewalls of the container to be decreased to the point where they become gas permeable. This is beneficial because it facilitates the diffusion of critical gas to and from the roller bottle without the use of additional membranes, openings, or extra design features.

2) Claims 1, 2, 5-12, 14, 16, 17, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 4912048) in view of Keilman (US 4717668).

With respect to claims 1 and 2, Smith discloses a roller bottle container for cell growth culturing comprising an elongate cylindrical wall (Figure 1:16) having a closed bottom end and a liquid opening at an opposing top end. The elongate cylindrical wall includes a plurality of longitudinally axial extending pleats (Figure 1:28) that at least partially extend from the closed end to the top end. This is disclosed in 3, lines 1-47. Additionally, Smith teaches in column 3, line 48 to column 4, line 19 that at least one circumferential rib (Figure 3:66) is provided along the cylindrical wall. The ribs intrinsically serve to structurally reinforce the wall, while performing a variety of other functions. Smith, however, does not expressly disclose that the ribs are integrally formed with the wall.

Keilman discloses a roller bottle container for cell growth culturing comprising a plurality of circumferential ribs (Figure 1:26) extending around the bottle. Column 1, line 60 to column 2, line 3 indicates that the ribs are formed integrally with the remainder of the flexible cylindrical wall that defines the roller bottle.

Smith and Keilman are analogous art because they are from the same field of endeavor regarding roller bottles.

At the time of the invention, it would have been obvious to equip Smith's roller bottle with a series of circumferential ribs that are integrally formed to the cylindrical wall of the container. Smith hints that such an alteration is feasible by stating in column 4, lines 8-19 that although removable ribbing is preferable, it is possible to affix the ribbings to the container sidewall. Keilman states in column 3, line 55 to column 4, line 5 state that integrally formed ribbings are beneficial because they serve to increase the rigidity of the bottle, and decrease the likelihood that the bottle will collapse during use. The increased stability caused by the ribbings allows the width of sidewalls of the container to be decreased to the point where they become gas permeable. This is beneficial because it facilitates the diffusion of critical gas to and from the roller bottle without the use of additional membranes, openings, or extra design features.

With respect to claim 5, Smith and Keilman disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. In addition, Smith discloses that the top neck portion of the container includes integral external screw threads for receiving an internally screw threaded cap thereon. This is taught in column 3, lines 38-47.

With respect to claims 7-9 and 11, Smith and Keilman disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. In addition, Smith

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discloses that the pleats define a plurality of opposed facing internal surfaces for the formation of cell growth thereon. This is taught in column 2, lines 4-17. Figure 2 indicates that each of the pleats includes a first sidewall extending between a first end point and a first apex (Figure 4:62), and a second sidewall extending between a second end point and the first apex. The first apex is located radially further from a longitudinal center of the container than the first and second end points. The first and second sidewalls are convergently disposed relative the first apex. Furthermore, a juncture is defined between adjacent pleats with the second end point of a first pleat being connected to the first end point of a second pleat, wherein the juncture defines a second apex (Figure 4:60). Again, this is apparent from Figure 2.

With respect to claims 10, 12, and 14, Smith and Keilman disclose the apparatus set forth in claims 9 and 11 as set forth in the 35 U.S.C. 103 rejections above. Although Smith and Keilman do not expressly disclose specific angle measurements and separation distances that define the geometry of the pleats, it would have been obvious to construct the pleats to meet the claimed limitations. Varying the geometry of the pleats to achieve the most favorable design is simply the optimization of result effective variables that could be pursued using routine experimentation. In the absence of new or unexpected results, it would have been obvious to ensure that the first and second sidewalls define an angle of 60 degrees therebetween, that the first apices of two adjacent pleats are separated by an angle of 9 degrees, and that the second apices of two adjacent pleats are separated by a distance of 0.80 cm to 0.85 cm. This would

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guarantee that the cells in solution are provided with an adequate opportunity to attach to the surface of the pleated sidewall. The manipulation of the geometry of the pleated surface is simply the act of experimenting with the roller bottle's available surface area in an effort to optimize cell adhesion. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

With respect to claims 16 and 17, Smith and Keilman disclose the apparatus set forth in claim 9 as set forth in the 35 U.S.C. 103 rejection above. In addition, Smith discloses that the ribs include outer walls (Figure 4:68) that extend radially outwardly from the pleats, and are flush with the outermost portions of the first apices (Figure 4:62) of the pleats. Keilman also discloses ribs that comprise outer walls that extend radially outwardly from the surface of the cylindrical sidewalls of the container. When combined with the pleated structure disclosed by Smith, it is clear that these ribs would maintain an outer wall that extends outwardly from the pleats and is flush with the outermost portions of the first apices of the pleats. Likewise, it would have been obvious to incorporate an inner wall extending radially inwardly from the pleats so that the inner wall is flush with the innermost portions of the second apices. This inner wall would complement the outer wall in providing increased support to the cylindrical walls of the container.

With respect to claims 19 and 20, Smith and Keilman disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. Although Smith and

Keilman do not expressly disclose the number of ribs that are on the container, it would have been obvious to construct the container so that it includes three or four ribs. Varying the number of ribs to achieve the most structurally stable design is simply the optimization of a result effective variable that could be pursued using routine experimentation. In the absence of new or unexpected results, it would have been obvious to ensure that the container included enough ribs so that it was protected against deformation, but not so many that the container would become overly rigid. This would guarantee that the roller bottle is capable of maintaining its shape during incubation and culturing procedures. Keilman, in Figure 1, depicts a roller bottle comprising six ribs, so the construction of a roller bottle with three or four ribs is certainly feasible. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

3) Claims 3, 4, 13, 15, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 4912048) in view of Keilman (US 4717668) as applied to claims 1, 9, and 11, and further in view of Serkes (US 4962033).

With respect to claims 3, 4, and 18, Smith and Keilman disclose the apparatus in claim 1, however do not expressly disclose that the cylindrical wall further includes at least one unpleated longitudinal section defining a drain panel.

Serkes discloses a roller bottle comprising a pleated midsection (Figure 1:14) that includes a plurality of drain channels (Figure 4:22). This is disclosed in column 4, lines 4-38. Figure 2 illustrates one embodiment of the invention in which the cylindrical

wall includes two diametrically opposed unpleated longitudinal sections (Figure 2:24 and Figure 2:22), each defining a drain panel.

Smith, Keilman, and Serkes are analogous art because they are from the same field of endeavor regarding roller bottles.

At the time of the invention, it would have been obvious to utilize the drain panels disclosed by Serkes in the device proposed by Smith and Keilman so that the ribs are flush with the outermost portion of the drain panel. Serkes teaches in column 3, lines 16-47 that drain panels represent a critical feature of roller bottles in that they facilitate the removal of liquids and cells that would otherwise remain trapped in the pleated sections during collection procedures. Drain panels also function as beams that prevent bending, extension, and compression of the pleats during handling and incubation. It would have been obvious to ensure that the ribs disclosed by Smith and Keilman abut and are flush with the drain panel disclosed by Serkes in order to make sure that every vertical section of the roller bottle is stabilized by either a rib or a drain panel.

With respect to claims 13 and 15, Smith and Keilman disclose the apparatus in claims 9 and 11, however do not expressly disclose that the first and second apices are rounded.

Serkes discloses a roller bottle comprising a pleated midsection (Figure 1:14) that includes a plurality of drain channels (Figure 4:22). This is disclosed in column 4, lines 4-38. In addition, Serkes teaches in column 4, lines 39-54 that the pleats are rounded. Specifically, Serkes teaches that the first apices (Figure 3:40) are rounded

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and is silent as to the shape of the second apices (Figure 3:42). However, Figure 3 indicates that both sets of apices are constructed with essentially the same degree of sharpness, and that both are rounded.

At the time of the invention, it would have been obvious to round off the first and second apices of the pleats disclosed by Smith and Keilman. Serkes teaches in column 4, lines 39-54 that rounded edges are easier for cells to stick to, as opposed to sharp or pointed surfaces. Since both the first and second apices are intended to facilitated cell adhesion, it would have been apparent to ensure that both sets of apices were round in shape. Serkes further points out that rounded junctures are beneficial because they are easier to form by casting and molding, and that rounded surfaces are stronger and less subject to cracking on flexing.

4) Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 4912048) in view of Keilman (US 4717668) as applied to claim 5, and further in view of O'Connell (US 4763804).

Smith and Keilman disclose the apparatus in claim 5, however do not expressly disclose that the neck portion includes a locking arrangement for holding a cap in a locked open position on the container for maintaining the container open to an environment.

O'Connell discloses a cap and a container for cell growth culturing comprising a top end with a locking arrangement (Figure 4:20) for holding a cap (Figure 4:30) in a locked open position. This is described in column 2, line 62 to column 3, line 17.

Smith, Keilman, and O'Connell are analogous art because they are from the same field of endeavor regarding the culturing of cell samples.

At the time of the invention, it would have been obvious to incorporate the locking arrangement disclosed by O'Connell in the apparatus disclosed by Smith and Keilman. O'Connell states in column 1, lines 6-26 that it is important to include a locking arrangement in many cell growth culturing devices that causes the device to remain locked in an open position. O'Connell states that this is due to the fact that during autoclaving, containers must be open in order to permit the interior to be fully sterilized. Further, it is necessary for the container to be open during incubation to prevent an undesirable positive pressure at the interior, as well as during cooling periods to prevent unwanted negative pressures. It is also important to maintain an opened position during cell culturing in order to permit the diffusion of critical gases to and from the cells.

5) Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 4912048) in view of Keilman (US 4717668) as applied to claim 11, and further in view of Sugiura (US 4749092).

Smith and Keilman disclose the apparatus in claim 11, however do not expressly disclose that the ribs include an inner wall that extends radially inwardly from the pleats, wherein the inner wall is flush with the innermost portions of the second apices of the pleats.

Sugiura discloses a container comprising a plurality of longitudinally extending pleats (Figure 1:6) that serve to strengthen the bottle against deformation. This is

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disclosed in column 2, lines 34-53. Figure 3 illustrates that a circumferential rib is provided which comprises an inner wall that extends radially inwardly from the pleats, and is flush with the innermost portion of the second apices of the pleats.

Smith, Keilman, and Sugiura are analogous art because they are from the same field of endeavor regarding the use of pleats and ribs to increase the strength of bottles.

At the time of the invention, it would have been obvious to supply an inner wall flush with the innermost portions of the pleats to the apparatus disclosed by Smith and Keilman. This additional facet of the rib would compliment the existing outer wall as a mechanism to further strengthen the pleated sidewalls of the container against deformation. A rib comprising an inner sidewall could be constructed inexpensively without detracting from the functionality of the pleated cell culture bottle.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Serkes (US 5151366), Meder (US 5866419), and Harris (US 5373961) reference teach the state of the art regarding containers with ribs and/or pleats.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on (571) 272-1226. The fax phone

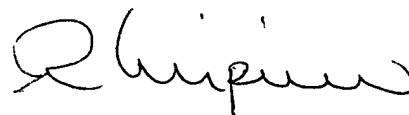
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number for the organization where this application or proceeding is assigned is 571-273-8300.

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